PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Morey Kraus et al.	Confirmation Number:	5973
Serial No.:	09/698,893	Art Unit:	1632
Filed:	October 27, 2000	Examiner:	Anne Marie Falk
Customer No.:	21559		
Title:	METHODS FOR IMPROVING CENTRAL NERVOUS SYSTEM FUNCTIONING		

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Commissioner for Patents
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DECLARATION OF MOREY KRAUS
UNDER 37 C.F.R. § 1.132

I, Morey Kraus, declare:

1. I am currently the Vice President and Chief Technical Officer at ViaCell, Inc., which is a biotechnology company I founded and which is a co-owner of the above-referenced application. I have over 10 years of experience working with umbilical cord blood cells.

2. I have read and understood the Office Action, dated April 23, 2007, which was mailed in connection with U.S. Serial No. 09/698,893. This Declaration is presented to overcome the rejection of claims 1-3, 5-11, 13, 15, 19-21, 25, 27, 29-33, 35, 37, 41, and 44 under 35 U.S.C. § 112, first paragraph, for lack of written description and enablement.

3. The designation "CD34+/-, Lin-," which is used in the present specification to refer to a population of cells to be administered to a patient to improve central nervous system function (e.g., to treat stroke), is a shorthand form for describing a population of cells that lack

the expression of lineage markers (e.g., CD2, CD3, CD14, CD16, CD19, CD24, CD56, CD66b, glycophorin A) and that express or lack expression of CD34; the designation refers to phenotypic expression of cell surface markers, not genotypic expression. The cell population referred to by this designation is clear and unambiguous, and would be recognized by one skilled in the art as referring to a population of cells that includes both "CD34+, Lin- cells" and "CD34-, Lin- cells."

4. The specification of the above-captioned application provides ample guidance and instruction such that one of ordinary skill in the art can prepare CD34+/-, Lin- cells for use in the methods of present claims 48-55. In particular, the specification teaches that CD34+/-, Lin- cells can be isolated using the methodology described in Example 5 of U.S. Patent No. 5,925,567 (the "'567 patent"). Example 5 of the '567 patent teaches the isolation of CD34+/-, Lin- cells using negative selection by utilizing an "[a]ntibody/anti-dextran cocktail composed of the following selection molecules: CD2, CD3, CD14, CD16, CD19, CD24, CD56, CD66b and glycophorin A at concentrations between 0.5 and 1.25 μg/μl each" (see col. 17, lines 1-5, of the '567 patent). The population of cells that results from the negative selection method described in Example 5 of the '567 patent is a population of cells described in the present specification as CD34+/-, Lin- cells. The specification of the '567 patent states that the negative selection method produces a population of cells having a "relative increase in CD34+ cells" (i.e., CD34+, Lin- cells; see col. 18, lines 7-10). This is so because the negative selection method removes all lineage positive cells; it does not, though, remove CD34- cells that are also Lin- (i.e., CD34-, Lin- cells). Thus, the negative selection method described in Example 5 of the '567 patent produces an isolated population of CD34+/-, Lin- cells, which is the population of cells described in the specification

and claims of the present application.

5. The specification teaches the isolation and use of human CD34+/-, Lin- cells from blood (e.g , cord blood and peripheral blood) to treat conditions such as stroke. This is plainly described in connection with cord blood on page 2, lines 24-25, of the present specification Furthermore, the Example described on pages 10-13 of the present specification involved experiments in which CD34+/-, Lin- cells isolated from fresh human cord blood were administered to Sprague Dawley rats subjected to middle cerebral artery (MCA) occlusion. We used this rat stroke model to demonstrate that the administration of human CD34+/-, Lin- cells by injection directly to the site of the stroke would promote an improvement in CNS function as compared to MCA-occluded rats administered vehicle alone; two behavioral tests, the forelimb placing test and the hindlimb placing test, confirmed an improvement in CNS function following the administration of human CD34+/-, Lin- cells to MCA-occluded rats. Because the rat MCA occlusion model described in the present specification is art-recognized as being predictive of success in treating stroke in humans, the statistically significant results of improvement in the MCA-occluded rat model reported in the present specification plainly support the enablement of present claims 48-55

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon

10/29/07
Date

Morey Kraus